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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.         | CONFIRMATION NO. |
|---|-------------|----------------------|-----------------------------|------------------|
| 10/719,049  | 11/21/2003  | John Rees            | UDL-108 D1                  | 3295             |
| 36822 7590 03/08/2007<br>GORDON & JACOBSON, P.C.<br>60 LONG RIDGE ROAD<br>SUITE 407<br>STAMFORD, CT 06902 |             |                      | EXAMINER<br>BEX, PATRICIA K |                  |
|   |             |                      | ART UNIT                    | PAPER NUMBER     |
|   |             |                      | 1743                        |                  |
| SHORTENED STATUTORY PERIOD OF RESPONSE  |             | MAIL DATE            | DELIVERY MODE               |                  |
| 3 MONTHS  |             | 03/08/2007           | PAPER                       |                  |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

# Office Action Summary

Application No.

10/719,049

Applicant(s)

REES, JOHN

Examiner

P. Kathryn Bex

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 28 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 75-105 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 75-105 is/are rejected.
- 7) ☒ Claim(s) 81 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 November 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☒ Certified copies of the priority documents have been received in Application No. 09/440,787.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 3/9/2004
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Drawings*

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "first flow path" and "second flow path" in claim 75, "the portion" of the elongate sheet or strip in claims 87 and 89, the "matrix" in claims 93-95, "store of mobile phase" in claim 101, the "separate container for mobile phase" in claim 102, the "second path including at least part of said first flow path" in claim 103, the "second flow path includes substantially the entirety of said first flow path" in claim 104, the "plurality of flow paths..., wherein said plurality of flow paths are stacked" in claim 105, must be shown or the feature(s) canceled from the claim(s). For the sake of clarity, the Figures should include reference numbers that correspond to the aforementioned flow paths. No new matter should be entered.
2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "1" has been used to designate both the mobile phase and the reservoir. Additionally, reference no. "4" is both "immunoabsorbent" and "detection zone."
3. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet,

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and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Specification***

4. Applicant is reminded of the proper language and format for an abstract of the disclosure. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

5. The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). The area of the specification, beginning at page 24, line 25, where the claimed apparatus is taught does not describe the "first position" and "second position" of the detection zone, as recited in claim 75. Furthermore, the specification fails to teach: a "store of mobile phase" as recited in claim 101, "a separate container for mobile phase" as recited in claim 102, the "second flow path includes at least a part of said first flow path" as recited

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in claim 103, the "second flow path includes substantially the entirety of said first flow path" as recited in claim 104. Appropriate correction is required.

### ***Claim Objections***

6. Claim 81 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. In this case, claim 81 is identical to claim 80; both claims depend from claim 75. No claims depend from claim 81; thus, claim 81 appears needlessly tautological.

### ***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 76, 78, 82, 84, 103 and 104 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 76, line 2, recites --a first position--, which should be changed to "said first position" for proper antecedent basis. Similarly, same line recites "a second position", which should be changed to --said second position-- for proper antecedent basis.

Claims 82 and 84 are confusing and indefinite. These claims merely state that the first and second path potentates flow towards the detection zone. It is not clear how

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this accomplished since no structure is recited in the claims. Clarification is respectfully requested.

With respect to claims 103-104, it is confusing and indefinite how the second flow path "includes" the at least part or substantially the entirety of the first flow path. This is neither taught in the instant specification, nor shown in the Figures.

***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 75-91, 99-105 are rejected under 35 U.S.C. 102(b) as being anticipated by Bunce et al. (US Patent No. 5,198,193).

Bunce et al., teach an immunoassay analytical test apparatus for screening for the presence of an analyte in a sample of body fluid (i.e., blood; col. 3, line 18; see also, Fig. 5 and Fig. 20 of Bunce et al.) The apparatus of Bunce et al., comprises:

(a) a first flow path 10e including a sample receiving zone for receiving the sample;

(b) a second flow path 20e including non immobilized labeled immunoreactive material that can interact with the analyte;

(c) a mobile phase receiving zone for receiving a mobile phase 61 from a separate container or store 60 (as recited in claims 101, 102). The mobile phase receiving zone being in communication with the first and second flow paths; and

(d) a detection zone 40e including immunoabsorbent 32a for binding the analyte present in the sample.

The detection zone of Bunce et al., is manually moveable in sequence from a first position in communication with the first flow path through expansible zone 23e to a second position in communication with the second flow path through expansible zone 24e (as recited in claims 76-78, and 91). Thus, when the detection zone is in its first position there is flow of the sample in the mobile phase from the sample receiving zone to the detection zone, whereby the analyte is allowed to substantially bind with the immunoabsorbent. Furthermore, when the detection zone of Bunce et al., is in its second position there is flow of the labeled immunoreactive material in the mobile phase to the detection zone, whereby the labeled immunoreactive material is allowed to substantially bind to the analyte, so as to provide an indication of the presence of the analyte in the sample (see Bunce et al., beginning at col. 5, lines 24-47.) The various reagents for use with the apparatus are described in Bunce et al., beginning at col. 12, line 32.

With respect to the "Markush-type" claims 79-81, the first flow path includes a material selected from the group consisting of unlabeled immunoreactive material being upstream of the sample receiving zone (see col. 3, lines 20-55).

Regarding claims 82-85, 99-100, the first and second flow paths of Bunce et al., potentiate flow towards the detection zone by capillary action (see col. 1, lines 37-42).

With respect to claims 86-89, written in a Markush format, Bunce et al., teach a material absorbent to the mobile phase as disclosed beginning at col. 1, line 37.

Regarding claim 90, the apparatus of Bunce et al., includes a sink 50 for collection of fluid exiting the detection zone.

Moreover, with respect to claims 103-105, Bunce teach the second path including substantially all of the first path when in communication with detection zone 40e. In addition, the first and second paths are "stacked" vertically (see Fig. 5.)

11. Claims 75-91, 99-105 are rejected under 35 U.S.C. 102(b) as being anticipated by May et al. (US Patent No. 5,275,785).

May et al., teach an immunoassay analytical test apparatus for screening for the presence of an analyte in a sample of body fluid (i.e., blood.) The apparatus of May et al., comprises:

- (a) a first flow path 4 including a sample receiving zone for receiving the sample;
- (b) a second flow path 3 including non immobilized labeled immunoreactive material that can interact with the analyte (col. 6, lines 55-62);
- (c) a mobile phase receiving zone for receiving a mobile phase 61 from a separate container or store 6 (as recited in claims 101, 102.) The mobile phase receiving zone being in communication with the first and second flow paths; and



(d) a detection zone 8 including immunoadsorbent for binding the analyte present in the sample.

The detection zone of May et al., is manually moveable in sequence from a first position in communication with the first flow path through switch 11 to a second position in communication with the second flow path through expansible switch (as recited in claims 76-78, and 91). Thus, when the detection zone is in its first position there is flow of the sample in the mobile phase from the sample receiving zone to the detection zone, whereby the analyte is allowed to substantially bind with the immunoadsorbent. Furthermore, when the detection zone of May et al., is in its second position there is flow of the labeled immunoreactive material in the mobile phase to the detection zone, whereby the labeled immunoreactive material is allowed to substantially bind to the analyte, so as to provide an indication of the presence of the analyte in the sample.

With respect to the "Markush-type" claims 79-81, the first flow path includes a material selected from the group consisting of unlabeled immunoreactive material being upstream of the sample receiving zone (see col. 6, lines 55-62).

Regarding claims 82-85, 99-100, the first and second flow paths of May et al., potentiate flow towards the detection zone by capillary action (see col. 8, lines 2-4).

With respect to claims 86-89, written in a Markush format, May et al., teach a material absorbent to the mobile phase as disclosed beginning at col. 1, line 37.

Regarding claim 90, the apparatus of May et al., includes a sink 9 for collection of fluid exiting the detection zone.

Moreover, with respect to claims 103-105, May et al., teach the second path including substantially all of the first path when in communication with detection zone. In addition, the first and second paths are "stacked" horizontally (see Fig. 1.)

### ***Claim Rejections - 35 USC § 103***

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. Claims 92-98 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bunce et al. (US Patent No. 5,198,193) or May et al. (US Patent No. 5,275,785) in view of Burd et al. (US Patent No. 5,939,331).

The teachings of Bunce et al., and May et al., have been summarized previously, *supra*.

Neither Bunce et al., or May et al., explicitly teach the analyte is allergen specific IgE (claim 92) or the removal of non-IgE components via a matrix or filter located between the sample inlet and the detection zone. However, the use of lateral flow assay for the IgE analyte in whole blood employing a filter is considered conventional in the art, see Burd et al.

Burd et al., teach a lateral flow device for detecting the presence of analytes (including IgE). The flow device includes a filter containing a matrix (i.e., red blood cell binding reagents) located at the sample receiving zone 23 between the sample introduction aperture 35 and the detection zone 29 (see col. 9, line 57- col. 10, line 14 and col. 7, lines 41-51). The filter is designed to remove the red blood cells since whole blood sample may obscure the reading of the test results due to turbidity and color (col. 1, lines 19-20.)

Thus, it would have been obvious to one of ordinary skill in the art at the time of the claimed invention to have included in the lateral flow device of Bunce et al., or May et al., the filter containing matrix of Burd et al., in order to remove the red blood cells since whole blood sample may obscure the reading of the test results due to turbidity and color (col. 1, lines 19-20.)

### ***Conclusion***

15. No claim allowed.

16. Any inquiry concerning this communication or earlier communications from the examiner should be directed to P. Kathryn Bex whose telephone number is 571-272-

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2374. The examiner can normally be reached on Monday thru Thursday, 9 AM to 6 PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

17. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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